REMARKS

Applicants respectfully requests entry of the Amendment and reconsideration of the claims. Claim 11 has been amended, and new claim 17 has been added. Support can be found throughout the specification, including page 8, lines 11-15. No new matter has been added through the amendment. Claims 1-10 and 14-16 have been cancelled. Claims 11-13 and 17 will be pending upon entry of this amendment. Applicants respectfully request reconsideration and withdrawal of the pending rejections under 35 U.S.C. §§ 102(b), 102(e), 103(a), 112, first and second paragraphs.

Rejection Under 35 U.S.C. § 102(b/e)

The Examiner rejects claims 9-10 and 14-15 under 35 U.S.C. § 102(b) and § 102(e). Applicant has cancelled claims 9-10 and 14-15 thereby rendering the rejection moot. Applicant respectfully requests removal of these rejections.

Rejection Under 35 U.S.C. §103(a)

Claims 11-13 are rejected under 35 U.S.C. § 103(a) as unpatenable over Adams et al., Papandreou et al., Salzman et al., Klokkers-Bethke et al., and Veronesi et al. Further, the Examiner states that the test for determining patentability of kit claims relates to the functionality of the printed matter, citing *In re Ngai* and *In re Gulack*. To establish a *prima facie* case of obviousness, three criteria must be met—a suggestion or motivation to combine references, a reasonable expectation of success, and the prior art reference teaches or suggests all the claim limitations. MPEP §2143; *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991). Applicant respectfully traverses the rejection.

The Examiner states that the instructional materials are not functionally related to the nitric oxide donor or agonist compositions because these compositions can function as an active effective drug even in the absence of instructional material. However, in making this objection, the Examiner fails to note that the instructional materials claimed recite administering the composition to ameliorate symptoms of insulin resistance. In the absence of instructional material, one in possession of the composition of the invention would not be motivated, taught, or enabled to administer the compositions of the invention to one suffering from insulin

resistance. Therefore, Applicant respectfully maintains that the instructional material is functionally related to the compositions and does patentably distinguish the claimed compositions over the prior art.

Applicant has amended claim 11. Applicant submits that the printed matter described in claim 11, step (b) is functionally related to the substrate since it specifies how the composition is to be administered. Applicant submits that the instructions and the functional language in those instructions provide instructions to make the invention work. Applicant kindly directs the Examiner to page 30, lines 10 though 16 (Example 3) where insulin resistance is not reversed by administration of a nitric oxide donor intravenously but is fully reversed by administration of the same dose to the liver via the portal vein. One would appreciate that the human circulatory system provides for uptake from the gastrointestinal system to the heptatic artery/portal vein for delivery to the liver. Thus, Applicant respectfully asserts that the limitation "by oral administration of the composition" to be included in the directions in the kit is supported by the specification and contributes to the functionality of the kit.

The Examiner has also rejected claim 16 stating that it would have been obvious to one of ordinary skill in the art at the time the invention was made to form a composition containing a combination of a nitric oxide donor and a nitric oxide agonist because one of ordinary skill in the art would reasonably expect the additive effect of the two compounds to effectively increase production or release of nitric oxide in a patient in need thereof. Applicant respectfully asserts that the use of nitric oxide donors or nitric oxide agonists targeted to the liver to ameliorate the symptoms of insulin resistance was unknown at the time of filing. None of the references, alone or in combination, teach or suggest a composition comprising a nitric oxide donor and/or nitric oxide agonist, wherein the composition is structurally modified to preferentially release nitric oxide in the liver.

Based on the forgoing, Applicant submits the Examiner has failed to establish a *prima facie* case of obviousness. The cited references, alone or in combination, do not disclose all the elements of Applicant's claims. None of the references, alone or in combination, teach or suggest formulating the claimed compositions targeted to the liver into a kit with instructions for ameliorating symptoms of insulin resistance. Accordingly, withdrawal of the rejection under §103(a) is respectfully requested.

Rejection Under 35 U.S.C. § 112, first paragraph

The Examiner rejects claim 16 under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement. Specifically, the Examiner has stated that there is no support in the applicant's specification for a combination composition comprising a nitric oxide donor and a nitric oxide agonist. Applicant respectfully traverses as it may apply to new claim 17, claim 16 having been canceled.

As noted in the Guidelines for Examination of Patent Applications Under 35 U.S.C. § 112, ¶1, "Written Description" Requirement ("the guidelines"), there is a "strong presumption" that an adequate written description of the claimed invention is present when the application is filed, 66(4) *Fed Reg.* 1099, 1105 (2001); *see also, In re Wertheim,* 191 USPQ 90,97 (CCPA 1976). The guidelines further state that "[(The examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims." 66(4) *Fed. Reg.* at 1107; 191 USPQ at 97, (emphasis added). Compliance with the written description requirement does not require an applicant to describe exactly the subject matter claimed; rather, the description must clearly allow a person of ordinary skill in the art to recognize that he or she invented what is claimed. *Vas-Cath Inc. v. Mahurkar,* 19 USPQ2d 1111, 1116 (Fed. Cir. 1991). The test is whether the originally filed specification reasonably conveys to a person having ordinary skill in the art that applicant had possession of the subject matter later claimed. *In re Kaslow,* 217 USPQ 1089 (Fed. Cir. 1991). Moreover, in order to have possession of members of a claimed genus, the specification need not describe all of the species that the genus encompasses. *Amgen Inc. v. Chugai Pharmaceutical Co.,* 18 USPQ2d 1016, 1027 (Fed. Cir. 1991).

Applicant respectfully submits that support for a nitric oxide donor is clearly found in the specification. For example, at page 8, line 11-12, Applicant states that "[c]ompounds of the present invention can be considered, generally, as members of the groups of nitric oxide agonists and NO donors." Applicant submits that since "and" was used, instead of "or", combination compounds are disclosed. Applicant respectfully asserts that a combination of a nitric oxide agonists and a nitric oxide donor is clearly supported in the specification.

In view of the foregoing, Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph.

Rejections Under 35 U.S.C. § 112, second paragraph

The Examiner rejects claims 15-16 under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite. Applicant respectfully traverses.

Claim 15 is rejected for allegedly having insufficient antecedent basis for the limitation "said insulin activity". Claim 15 has been cancelled, thus rendering the rejection moot.

The Examiner rejects claim 16 for allegedly having insufficient antecedent basis for the limitation " a nitric oxide donor and a nitric oxide agonist". Claim 16 has been cancelled, thus rendering the rejection moot. However, claim 17 recites similar but not identical language. Applicant respectfully asserts that the rejection for lack of antecedent basis has been incorrectly applied.

> A claim is indefinite when it contains words or phrases whose meaning is unclear. The lack of clarity could arise where a claim refers to "said lever" or "the lever," where the claim contains no earlier recitation or limitation of a lever and where it would be unclear as to what element the limitation was making reference. MPEP 2173.05(e).

The limitation " a nitric oxide donor and a nitric oxide agonist" is clear and definite. It is not a limitation that recites language such as "said" or "the" to refer to a previous recitation. As such, Applicant respectfully requests the removal of the rejections under 35 U.S.C. § 112, second paragraph.

CONCLUSION

In view of the above amendments and remarks, Applicants respectfully requests a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

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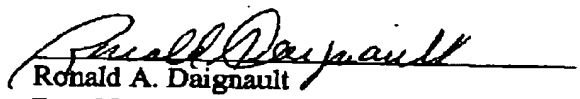
Date: July 19, 2005



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